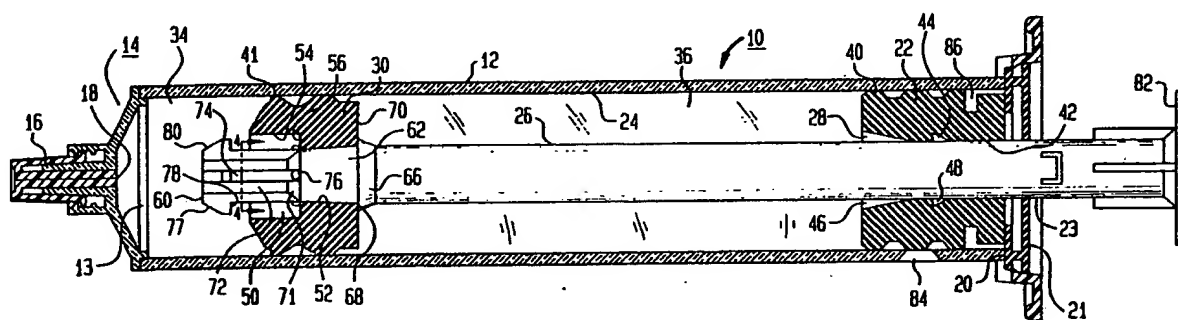




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁴ : A61M 5/315	A1	(11) International Publication Number: WO 88/ 09679 (43) International Publication Date: 15 December 1988 (15.12.88)
(21) International Application Number: PCT/US88/01801 (22) International Filing Date: 27 May 1988 (27.05.88) (31) Priority Application Number: 058,058 (32) Priority Date: 4 June 1987 (04.06.87) (33) Priority Country: US (71) Applicant: THE BOC GROUP, INC. [US/US]; 100 Mountain Avenue, Murray Hill, New Providence, NJ 07974 (US). (72) Inventors: McNEIRNEY, John ; 9 Springwood Circle, Madison, WI 53717 (US). HUCK, Charles, M. ; Box 114, Pottersville, NJ 07979 (US). (74) Agent: MELLER, Michael, N.; P.O. Box 2198, Grand Central Station, New York, NY 10163 (US).		(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), DK, FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), NO, SE (European patent). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: HYPODERMIC SYRINGE



(57) Abstract

A hypodermic syringe (10) comprises a barrel (12), a plunger (26) extending into the barrel through a stopper (22), and a piston (30) mounted on the plunger within the barrel. The piston selectively divides the barrel into two compartments (34) and (36) for storage of separate substances, the piston having an opening (54) therethrough which is either closed or opened by the plunger depending upon the position of the plunger relative to the piston. The plunger includes two stops (66) and (77) for controlling movement of the piston relative to and with the plunger, and a third stop (76) for releasably restraining movement of the piston relative to the plunger. The plunger is mechanically lockable to the rear stopper to cause movement of the stopper with the plunger during use of the syringe. In one embodiment, the stop (77) at the plunger leading end is pointed to facilitate assembly of the piston onto the plunger.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	KR	Republic of Korea
AU	Australia	LI	Liechtenstein
BE	Belgium	LK	Sri Lanka
BG	Bulgaria	LU	Luxembourg
BR	Brazil	MC	Monaco
CF	Central African Republic	MG	Madagascar
CG	Congo	MR	Mauritania
CH	Switzerland	MW	Malawi
CM	Cameroon	NL	Netherlands
DE	Germany, Federal Republic of	NO	Norway
DK	Denmark	RO	Romania
FI	Finland	SD	Sudan
FR	France	SE	Sweden
GA	Gabon	SN	Senegal
GB	United Kingdom	SU	Soviet Union
HU	Hungary	TD	Chad
JP	Japan	TG	Togo
KP	Democratic People's Republic of Korea	US	United States of America

-1-

HYPODERMIC SYRINGEFIELD OF THE INVENTION

This invention relates to hypodermic syringes, and particularly to the type which are disposable, which contain two chambers for the separate storage of two different substances, and which include valve means allowing mixing of the two substances immediately prior to injection.

BACKGROUND OF THE INVENTION

Hypodermic syringes of this type are generally known. U.S. Patent No. 3,076,456, to Hunt, for example, shows (FIGS. 13 and 14) a syringe including a barrel which is sub-divided into two separate chambers by means of a piston which is in sealed and slideable relation with the inside wall of the barrel. The piston contains a tapered central opening which cooperates with a tapered plug portion of a plunger which extends into the barrel from one end thereof and which extends through the piston. When the plunger is moved forward relative to the piston, the plug portion of the plunger enters into and seals the piston opening. When the plunger is retracted, the piston opening is unsealed thereby providing communication between the two chambers and the mixing of the contents

-2-

thereof. Upon further retraction of the plunger, a stop means, comprising a rod threaded through the plunger transverse to its longitudinal axis, engages a face of the piston, whereby the piston can be retracted with the plunger to an end of the barrel. This results in a single, combined chamber within the barrel and a complete mixing together of the formerly separated substances. Injection of the mixed substances is then achieved in normal fashion by advancing the plunger into the barrel, this movement again sealing the piston opening and allowing the piston to forceably eject the barrel contents through a needle attached to the other end of the barrel.

One potential problem with the Hunt syringe is that in a vibratory environment, e.g., during shipment of filled syringes, the tapered sealing plug can slip out of the tapered hole of the piston and the substance stored in the two chambers can prematurely mix. This can destroy the value of the mixture since it degrades with time and must be used relatively promptly after it is formed.

Similarly, for fixing the plunger to the piston, for retracting the piston with the plunger, a cross pin is used which must be inserted through the plunger end after it has been inserted through the piston during assembly of these parts. The use of the cross pin and the step of threading it through the plunger end add undesirable cost and complexity to the Hunt syringe.

A further problem with the Hunt syringe arises from the fact that during retraction of the plunger, the piston is always in its unsealed condition. Thus, this syringe cannot be used for positively drawing blood into the syringe through the needle (to determine, for example, if

the needle is properly inserted into a vein of a subject receiving an injection) by withdrawing the plunger to create a negative pressure within the barrel - the unsealed piston not allowing this.

While not known for certain, a solution (relevant to the solution provided by the present invention) for this last named problem may exist in a syringe shown in U.S. Patent 3,511,239 to Tuschhoff, the patent specification, however, not describing the blood drawing procedure. In the Tuschhoff patent, a piston is fixedly mounted on the end of a plunger, the seal of the piston with the inside wall of the barrel being such that the seal is broken upon retraction of the piston along the barrel. The syringe, however, also includes a stopper which seals the end of the barrel into which the plunger extends, the stopper being in sealed and slideable relation with both the plunger and the barrel inner wall. In use, the piston is retracted by the plunger to the rear end of the barrel, to allow complete mixing of the stored substances, and into face to face contact with the stopper. Then, when the piston is advanced to eject the substances, the stopper joins in this movement owing to the negative pressure formed between the piston and the stopper. It appears that once the piston engages the stopper, any further rearward movement of the piston (thereby unsealing it) would cause rearward movement of the stopper, the barrel seal of which is not affected by movement in either direction. Thus, a negative pressure within the barrel would be created, allowing positive drawing of blood. In the Tuschhoff syringe the liquid in one chamber must flow around the piston, which is closely fitted to the barrel, to enter the other chamber and mix with the substance in the other chamber. It is difficult to select the size of

-4-

the piston relative to the diameter of the barrel such that both a good seal during storage and a reasonable flow around the seal (the piston) during use are both achieved.

SUMMARY OF THE INVENTION

The present invention is directed to apparatus comprising a barrel having a discharge end and a grip end, a slideable piston disposed within the barrel, and a plunger extending into the barrel from the grip end through a stopper, a leading end portion of the plunger passing through an opening through the piston and cooperating with the piston so as to either seal or not seal the piston opening depending upon the position of the plunger portion relative to the piston. The plunger portion comprises two spaced-apart stops for engaging surface portions of the piston in order to both securely seal the piston opening and allow advancement of the piston, in its sealed condition, upon forward movement of the plunger. It further comprises a third stop which functions to engage with and retract the piston.

One apparatus of the present invention is a syringe designed such that it is relatively compact, allows two substances to be stored in isolated chambers until it is desired to mix them, and allows blood to be drawn back into the syringe to insure that a hypodermic needle attached to the discharge end of the syringe is in a vein of a subject being injected.

These and other features and advantages of the invention will be better understood from consideration of the following detailed description taken in conjunction with the accompanying drawing.

-5-

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a sectional view of a hypodermic syringe in accordance with one embodiment of the present invention; the syringe being in its filled, substance storing condition;

FIG. 2 is a partial view of the syringe shown in FIG. 1 showing the piston and the cooperating portion of a plunger in a portion of the barrel rearwardly from the position shown in FIG. 1;

FIG. 3 is a view similar to that of FIG. 2 but showing the piston retracted into engagement with the (barrel) stopper;

FIG. 4 is a cross-sectional view along line 4-4 of FIG. 1 showing details of an end portion of the plunger;

FIG. 5 is a view similar to that of FIG. 3 but showing the parts relationship during filling of the syringe.

FIG.'s 6, 7 and 8 are partial views of a syringe in accordance with another embodiment of the present invention; and

FIG. 9 is a cross-sectional view along line 9-9 of FIG. 6.

DETAILED DESCRIPTION

Referring now to FIG. 1, there is shown a hypodermic syringe 10 in accordance with the present invention and in a state prior to use, i.e., charged or filled with two separate substances which have not yet been mixed together. FIG.'s 2, 3 and 5 show partial views of syringe

-6-

10 f FIG. 1 with the components thereof in various positions and relationships with each other which occur during the use thereof. FIG. 4 shows a cross-sectional view along a line 4-4 of FIG. 1. Syringe 10 comprises a right-circular cylindrical barrel 12 comprising a discharge end assembly 14 comprising a nipple 16 having a small passageway 18 therethrough and arranged for connection, in a conventional manner, to a hypodermic needle (not shown). Discharge end assembly 14 is coupled to a discharge end 13 of syringe 10. The other end (grip end 20 of the barrel 12) is closed by a stopper 22, the radial side of which is in sealed relation with an inside wall 24 of the barrel. A plunger 26 extends through a central opening 28 through stopper 22 in slideable, sealed relation therewith. Grip end 20 of barrel 12 is sealed by a locking cap 21 which has a central opening 23 whose diameter is sufficient to allow plunger 26 to slidably pass therethrough. Mounted on the end of the plunger within barrel 12 is a piston 30, the radial side of which is in sealed and slideable relation with the inside wall 24 of barrel 12.

The piston 30 is movable with the plunger 26 within the barrel 12, and in the position shown in FIG. 1, the piston separates the inside of the barrel into two isolated compartments 34 and 36, each of which contains a different substance to be stored apart from the other until immediately prior to injection, when the substances, typically a liquid and a powder, are mixed together.

The stopper 22 is not fixed to an end 20 of the barrel 12, but is in slideable and sealed relation therewith. To this end, the stopper is provided, in known fashion, with a number of radially extending ridges 40 providing the desired mating relationship with the barrel.

-7-

The plunger 26 passes, as previously noted, through a central opening 28 through stopper 22. Opening 28 includes three segments of different cross-section, namely: a segment 42 having a right-circular cylindrical shape for sealing relation with the plunger (of same cross-sectional shape); a short length right-circular conical segment 44; and a longer length right-circular conical segment 46. The intersection of the two segments 44 and 46 provides a radially extending, annular surface 48. The purpose of the conical segments 44 and 46 and the surface 48 formed therebetween is described hereinafter.

As previously noted, the piston 30, in cooperation with the plunger 26, sub-divides the interior of the barrel into two isolated chambers 34 and 36. As with the stopper 22, the piston 30 includes a number of radially extending ridges 41 to provide a sealed and slideable relation between the piston and barrel. Also, piston 30 has a central opening 50 therethrough including segments of different cross-section, namely: a segment 52 (see, also, FIG. 2) of right-circular conical shape; and a segment 54 having a right-circular cylindrical shape, the diameter of the segment 54 being greater than that of the end of the segment 52 joined thereto and thus defining a radially extending annular surface 56.

A leading end 60 of the plunger 26 extends through the piston 30 and includes a number of different portions which cooperate with the piston. A first of these plunger portions is a plug portion 62 having a cross-section (conical) and length matching that of the conical opening segment 52 of the piston 30 for sealing shut the piston opening 50 when the plug portion 62 is disposed within the piston opening segment 52 (FIG. 1).

-8-

At the rear end of the plug portion 62 is an enlarged, conical portion 66 providing a radially extending, annular surface 68. In the condition shown in FIG. 1, the surface 68 is pressed against the surface 70 of the piston 30. The conical side of the plunger portion 66 is shaped to match the conical opening segment 44 of the stopper 22 to provide a force-fit, locked relation with the stopper. The conical portion 66 is also referred to as a "stop". The plunger portion 62 joins a short conical portion 71 of steeper slope leading to a right-circular cylindrical portion 72 having a diameter less than that of the smallest diameter portion of the piston opening segment 52. The purpose of this reduced diameter plunger portion 72 is to unseat the piston opening 52, thereby allowing communication between the two chambers 34 and 36, when the plunger plug portion 62 has been withdrawn from the piston opening 52 (see FIG. 2).

Disposed on the reduced diameter portion 72 of the plunger are a number (e.g., four) of axially and radially extending flanges 74, the rearward ends of which extend onto the conical portion 71 and terminate substantially flush with the leading end of the portion 62. Disposed on the rearward end of each flange 74 is a small hemispherical protrusion or "stop" 76. As shown in FIG. 1, when the plug portion 62 of the plunger is fully seated within the opening segment 52, thereby sealing it, the stops 76 are engaged with the annular surface 56, whereby the portion of the piston between the two piston surfaces 56 and 70 is clamped between the plunger stops 66 and 76. This serves to securely maintain the piston in its sealed condition.

At the forward end of the plunger portion 72, each flange 74 includes an end segment 77 of enlarged radial

extent, thereby providing a radially extending flat surface 78, which segments 77 then taper radially inwardly towards the plunger leading end 60.

Preferably, the various flange segments 74 are of identical shape and dimensions, whereby the four radially extending surfaces 78 thereof are disposed in a common plane perpendicular to the plunger axis, and the tapered surfaces 80 thereof comprise segments of a conical surface. The function of the four flange surfaces 78 (comprising a plunger "stop") is to engage the annular surface 56 within the piston 30 to cause retraction of the piston with the plunger, and the purpose of the flange tapered surfaces 80 is to facilitate threading of the plunger 26 through the piston 30 during assembly of the syringe.

The assembly and use of the syringe 10 are now described.

Plunger 26 is first threaded by leading edge 60 through the opening in stopper 22. Then plunger 26 and the piston 30 are assembled together by threading the leading end 60 of the plunger through the piston central opening 50. Although the maximum diameter D across the plunger portion 72 (see FIG. 5) is greater than the smallest diameter of the piston conical segment opening 52, the combination of the downwardly tapering surfaces 80 of the flanges 74 plus the resiliency of the piston (whose wall is preferably of rubber) allows the passage of the plunger 26 through the piston without tearing or disfiguring the segment 52 wall.

-10-

Discharge end assembly 14 is typically not attached to discharge end 13 during the filling of syringe 10.

To fill chamber 36 of barrel 12 with a substance, usually a liquid, a nozzle 85 (shown in dashed lines) from a container (not shown) of the substance is inserted into fill hole 84 with piston 30 and stopper 22 being positioned as shown in FIG. 5. The pressure of liquid flowing into barrel 12 causes piston 30 and plunger 26 to move away from the grip end of syringe 10 so as to define chamber 36 which houses the liquid. One advantage of this type of filling is that essentially no air escape hole is needed. Because stopper 22 is slideable relative to the barrel, a U-shaped clamp (not shown) is engaged at this time within a groove 86 (see FIG. 5) on the outside of the stopper 22 and against the barrel end to prevent movement of stopper 22 relative to barrel 12 during the time syringe 10 is being filled with liquid. Nozzle 85 and the U-shaped clamp are removed after syringe 10 is filled with liquid. Subsequently, plunger 26, stopper 22 and piston 30 are advanced towards the discharge end 13 of barrel 12 thereby sealing fill hole 84 as is shown in FIG. 1. The locking cap 21 is then put in place as is also shown in FIG. 1.

A second substance to be stored within syringe 10, generally a powder, is then poured through the discharge end 13 of the barrel 12 and into chamber 34. Discharge end assembly 14 is then coupled to the discharge end 13 of syringe 10. This coupling is typically accomplished by ultrasonic bonding.

Filled syringe 10 is now ready for shipment. One feature previously referred to is the presence of the

-11-

spherical stops 76. As shown in FIG. 1, when the plunger plug 62 is fully seated within the piston 30, the stops 76 engage the annular surface 56 of the piston. While the small stops 76 do not provide a large area engagement, some mechanical locking of the piston between these stops and the rear plunger stop 66 occurs which is sufficient to prevent unsealing of the piston relative to the plug during vibratory conditions. Also, when it is desirable to unseal the piston, the small area of the hemispherical stops 76, plus the rounded shape thereof, allows retraction of the stops 76 into the piston opening segment 52 with such little force as to not overcome the friction between the barrel and the piston 30, i.e., so as to allow the necessary relative movement between the plunger and the piston to unseal the piston opening. Piston 30 is essentially fixed in position when chamber 36 is filled with a liquid and no mixing action can occur until plunger 26 is pulled back far enough to allow the relationship between plunger 26 and piston 30 to be as is shown in FIG. 2.

When the syringe is to be used, the plunger is retracted, thereby first unsealing the piston (see FIG. 2) and then retracting the piston rearwardly along the barrel. As the piston 30 is retracted, the fluid in the rear chamber 36 is forced through the piston opening 50 thereby causing mixing together of the substances stored in the two chambers. The two former chambers now merge into a single chamber. Also, during such retraction, the flanges 74 on the plunger portion are forced into the piston opening segment 52, thereby ensuring the presence of open channels for fluid flow between the piston and the plunger.

-12-

The piston 30 is drawn all the way back to the stopper 22 (see FIG. 3) and the rear stop 66 on the plunger 26 is forced into the stopper through the opening segment 46 (the stopper wall being compressed to allow passage) and into the opening segment 44 where the stopper wall snaps into place around the stop. This locks the stopper to the plunger. Also, at this time, the piston has been brought into contact with the stopper and protective cap 16 is removed and a needle (not shown) is attached. Now plunger 26 is advanced somewhat to cause some of the mixture to exit through the needle so as to remove any residual air from the chamber and/or needle.

Then, after insertion of the needle (which has been added to the nipple end of the barrel) into the body of the subject to be injected, the plunger is advanced, thereby advancing both the stopper and the piston to eject the mixture of the two substances contained in the syringe through the needle and into the subject.

Because, at this time, the stopper has been locked to the plunger, any rearward movement of the plunger also retracts the stopper. This creates a negative pressure within the barrel, whereby blood can be positively drawn into the barrel as a test to determine if the needle had been properly inserted into a vein of the subject being injected.

One example of substances which can be stored and mixed in syringe 10 are thiopental sodium in powder form and water. A mixture of thiopental sodium is not stable and must be relatively promptly used. Syringe 10 allows thiopental sodium and water to be mixed in exactly the right proportions in a simple, efficient and safe manner.

-13-

In one illustrative embodiment of the invention, syringe 10 is designed to hold approximately 25 c.c. of liquid and 6 c.c. of powder and is approximately 6.43 inches long in the filled position with barrel 12 having outer and inner diameters of 1.037 inches and .937 inches, respectively. Barrel 12 is glass or plastic, locking cap 21 is plastic, and stopper 22 and piston 30 are both butyl rubber.

Referring now to FIG. 6, there is shown a preferred embodiment of a hypodermic syringe 100 in accordance with the present invention and in a state prior to use, i.e., charged or filled with two separate substances which have not yet been mixed together. FIG.'s 7 and 8 show partial views of syringe 100 of FIG. 6 with the components thereof in various positions and relationships with each other which occur during use thereof. FIG. 9 shows a cross-sectional view along a line 9-9 of FIG. 6. The differences between the syringe 100 of this embodiment and the syringe 10 of FIG. 1 are mainly in the piston and the portions of the plunger cooperating therewith. Accordingly, where not described, details of the syringe 100 are very similar or essentially identical to those of syringe 10.

With reference FIG. 6, the piston 102 has an opening 104 therethrough including two segments; a right-circular cylindrical segment 106 and a right-circular conical segment 108; an annular piston surface 110 being provided between the two segments.

In this embodiment of the invention, the leading end 112 of the plunger, which extends through the piston, is of generally constant cross-section (of right circular

-14-

cylindrical shape) and includes three spaced-apart stops; namely, a first stop 66 similar to the first stop 66 of the syringe 10, a second stop 114 similar to the first stop 66 but of slightly smaller maximum diameter, and a third stop 116 comprising a circular end-plate 117 providing a rearwardly facing annular surface 120, and a forwardly facing surface 122 of generally spherical shape.

The function of the two stops 66 and 114 is, as illustrated in FIG. 6, to clamp the two piston surfaces 110 and 70 between the stops and to seal the opening 106 through the piston. To this end, the diameter of the opening 106 is nominally equal to the diameter of the plunger portion 124 between the stops 66 and 114, thereby providing some degree of sealing of the opening, and the distance between the two stops 66 and 114 is somewhat less than the axial length of the opening 106, whereby, as shown, the conical surface of the stop 114 is wedged into the opening 106 thereby functioning as a stopper to seal the opening. Additionally, because of the wedging or clamping relation between the stops 66 and 114 and the piston, the piston is securely held in place on the plunger and not likely to be displaced during exposure of the syringe to a vibratory environment.

One function of the third stop 116 is to seal the piston opening segment 108 from the syringe forward chamber 34. Thus, as shown in FIG. 6, the diameter of the circular end plate 117 matches the diameter of the forward end of the opening segment 108 (actually, slightly larger to provide a wedged fit between the plate and opening wall) and the side surface 126 of the end plate 117 (see FIG. 7) is of conic shape corresponding to that of the opening 104. Sealing of the opening segment 108 provides

-15-

an added measure of sealing isolation between chambers 34 and 36.

A further function of the third stop 116 is to provide, in cooperation with the stop 114 and the portion 128 of the plunger extending between the two stops 116 and 114, paths for liquid to flow through the piston when the piston is in its unsealed condition, as shown in FIG. 7. To this end, a number of axially extending troughs or channels 130 (also seen in FIG. 9), are provided along the plunger portion 128 and partially along the two stops 114 and 116. Thus, as shown by the arrows in FIG. 7, liquid from the chamber 36 can enter the portion of the channels 130 where they extend along the stop 66, flow through the piston opening 106 along the plunger channels, and enter the piston opening segment 108 through the stop 116 channels.

As noted, the channels 130 extend only partially along the lengths of the stops 114 and 116. The reason for this is to avoid interfering with the sealing function of the stops. Thus, as shown in FIG. 6, when the piston is in its sealed condition, the channels along the stop 116 do not extend beyond the forward surface 132 of the piston, hence do not unseal the opening 108, and the channels along the stop 114 do not extend inwardly of the opening 106, hence do not unseal the opening 106.

The syringe 100 is assembled by first inserting a rear end of the plunger (without the thumb plate) through the piston 102 and threading the piston along the plunger to position it in its sealed condition, i.e., the piston surfaces 70 and 110 being clamped between the two stops 66 and 114 as shown in FIG. 6. Although this threading

-16-

process requires forcing the stop 66 through the opening 106, the conical surface of the stop 66 permits this without tearing or deforming the elastic material of the piston. The end of the plunger is then forced through the opening in stopper 22. The distance between the piston and stopper is adjusted so as to define the upper chamber length. The plunger, with the piston and stopper mounted thereon, is then inserted into the barrel until the stopper is just flush with the top of the barrel. Unlike the syringe 10 previously described, a filling hole is not provided through the barrel wall, and charging of the rear chamber 36 is accomplished by forcing a small diameter, rigid nozzle between the side of the stopper and the barrel wall and into the chamber 36 and injecting the chamber 36 contents therein through the nozzle. After filling, the nozzle is removed and the stopper 22 is fully inserted into the barrel. A powder charge is placed in the discharge end of the syringe barrel. After addition of the various barrel discharge and grip end sealing members and the thumb plate to the plunger end, the syringe is ready for storage and shipment.

Optionally, the plunger can be a two piece member with the pieces coupled together at a location close to the thumb plate. With such a two piece plunger it is possible to disassemble the plunger and to insert the longer end through the two rubber stoppers and to then reassemble the plunger.

The use of the syringe 100 is similar to that of the syringe 10. Thus, to unseal the piston, for mixing of the syringe ingredients, the plunger is retracted, thereby forcing the stop 114 through the piston opening 106 to the position shown in FIG. 7. The conical surface of the stop

-17-

114 allows such passage without axial movement of the piston. However, when the flat, rearwardly facing surface 120 of the third stop 116 engages the piston surface 110 further rearward movement of the plunger causes rearward movement of the piston. Thus, as previously described, the liquid contents of the rear chamber are forced through the unsealed, rearwardly moving piston into the front chamber.

As with the syringe 10, the piston 102 is moved into contact with the stopper 22 (FIG. 8), the stop 66 being wedged into the stopper opening 44 for locking the piston to the stopper. The plunger is then advanced to eject the mixed together ingredients from the syringe.

One difference in operation between the two syringes 10 and 100 is as follows:

A possible misuse of syringes occurs when the user does not retract the piston into a full surface and locked contact with the stopper 22. The problem caused by this is that some of the original liquid within the chamber 36 remains in the space between the piston and the stopper, hence is not forced through the piston and into contact with the powder. Incomplete mixing thus occurs.

With the syringe 10, when the plunger is then advanced, relative movement occurs between the plunger and the piston causing resealing of the piston. Thus, even though proper locking of the piston to the stopper has not occurred, whereby movement of the stopper does not occur upon advance of the piston, injection from the syringe occurs.

-18-

With the syringe 100, however, once the stop 114 has been forced rearwardly through the piston opening 106 to thereby unseal the piston (FIG. 7), subsequent forward movement of the plunger does not force the flat surface of the stop 114 back through the opening, but simply causes forward movement of the piston, but in its unsealed condition. Thus, while some ejection from the discharge end of the syringe is likely to occur, there is also a flow of ingredients from the forward chamber through the piston to the rear chamber. This is likely to be noticed by the user and is an indication that improper operation is occurring.

It is to be understood that the embodiments described herein are merely illustrative of the general principles of the invention. Various modifications are possible within the scope of the invention.

-19-

WHAT IS CLAIMED IS:

1. Apparatus comprising:

a barrel having a discharge end and a grip end;
means for sealing said grip end;

a plunger extending into said barrel through
said sealing means in sealed, slideable relation therewith;

a piston mounted on an end portion of said
plunger, said piston being selectively movable relative to
the plunger and being adapted to selectively isolate or
allow communication between compartments of the barrel on
opposite sides of the piston; and

the plunger comprises first, second and third
stops, the first and second stops defining end points of
movement between the plunger and piston, and the third
stop being disposed between the first and second stops and
being effective for releasably restraining said piston in
its sealed condition along said plunger.

2. The apparatus of claim 1 wherein said third stop
comprises at least one protrusion on said plunger, said
protrusion having a curved surface for engaging a surface
of said piston for restraining movement of said piston
relative to said plunger and for relatively easy movement
past said surface for allowing such movement.

3. The apparatus of claim 1 wherein each of said stops
is integral with said plunger, the stop at the leading end
of said plunger having a rearwardly facing surface for
engagement with said piston and a forwardly facing,
inwardly inclined surface facilitating force threading of
said plunger through an opening through said piston during
assembly of said piston onto said plunger.

-20-

4. The apparatus of claim 3 in which a portion of the leading edge of said plunger comprises a number of radially and axially extending flanges, each of which flanges comprises, at its forward end, a radially enlarged segment, the radial sides of which taper inwardly in the forward direction, the rearwardly facing, radially extending surfaces of said segments lying in a common plane and comprising the rearwardly facing surface of the plunger leading end stop and the radial sides of said segments comprising the inwardly inclined surface of said stop.

5. The apparatus of claim 4 wherein the apparatus is a syringe in which the discharge end is adapted to receive a hypodermic needle.

6. The syringe of claim 5 wherein:

the barrel is plastic or glass;
the means for sealing and the piston are both of a resilient material such as rubber; and
the plunger is plastic.

7. A syringe comprising a barrel having a discharge end adapted to receive a hypodermic needle and an grip end, a stopper sealing said grip end, a plunger extending into said barrel through said stopper in sealed, slideable relation therewith, and a piston mounted on an end portion of said plunger movable with and relative to said plunger, said piston being in sealed or communicating condition with barrel compartments on either side of said piston depending upon the position of said piston along said plunger, said stopper being in slideable relation with an inside wall of said barrel, a portion of said plunger towards a leading end thereof being lockable to said

-21-

stopper, whereby, upon retraction of said plunger for contacting and locking said portion to said stopper, said stopper is thereafter movable with said plunger.

8. The syringe of claim 7 wherein said locking portion of said plunger comprises an enlarged conical portion of decreasing diameter towards said stopper, and the opening through said stopper comprises a conical opening for receipt of said plunger conical portion in force-fit, locked relation.

9. A syringe comprising a barrel having a discharge end adapted to receive a hypodermic needle and an grip end, means for sealing said grip end, a plunger extending into said barrel through said sealing means in sealed, slideable relation therewith, and a piston mounted on an end portion of said plunger movable with and relative to said plunger, said piston being in sealed or communicating condition with barrel compartments on either side of said piston depending upon the position of said piston along said plunger, said plunger including three stops between which said piston is movable relative to said plunger, two of said stops defining the end points of such relative movement, and the third stop being disposed between the other two and being effective for releasably restraining said piston in its sealed condition along said plunger.

10. A syringe comprising a barrel having a discharge end and a grip end, a plunger extending, in sealed slidable relation, through said grip end into said barrel, a piston of resilient material mounted on said plunger for movement therewith within said barrel, said piston partitioning said barrel into two compartments, one of which is adapted to store a liquid, said piston having an opening

therethrough which is adapted to allow forced flow of stored liquid therethrough upon forced movement of said piston into said one compartment, said piston being moveable relative to said plunger between two portions thereof, one being a plug portion being adapted to mate with and seal said opening, the other being a portion having a cross-sectional extent less than that of said opening for unsealing it, said other portion including laterally extending protrusions for preventing collapse of the wall of said opening into sealed relation with said other portion upon forced movement of said piston, and said protrusions comprise a number of axially extending flanges defining along with surface areas of said flanges and the wall of said opening, communication channels for liquid flow along said other portion.

11. The apparatus of claim 1 in which one of said two stops is disposed rearwardly of said third stop in the direction of said grip end and the second of said two stops is disposed forwardly of said third stop in the direction of said discharge end, said third stop cooperating with said first stop for sealing an opening through said piston.

12. The apparatus of claim 11 in which each of said one and third stops comprises an enlarged conical portion of decreasing diameter towards said grip end permitting forced passage of said stops through said piston opening in a direction towards said grip end, and further comprising a radially extending surface adjacent to said conical portion in the direction of said discharge end preventing movement of said stops through said piston in a direction towards said discharge end.

-23-

13. The apparatus of claim 12 in which the end walls of said opening through said piston are clamped between the radially extending surfaces of said first and third stops for securing said piston to said plunger.

14. The apparatus of claim 12 in which the opening through said piston includes two axially extending, connected segments, ends of a first of said segments being sealed (when said piston is in its sealed condition) by said first and third stops, and an end of the second of said segments being sealed by said second stop.

15. The apparatus of claim 12 including at least one channel extending along said plunger and partially along said second and third stop, the distance between said second and third stops being at least equal to the axial length of said piston opening, and said channel providing communication between said barrel components through said opening when said second and third stops are disposed adjacent to opposite ends of said opening.

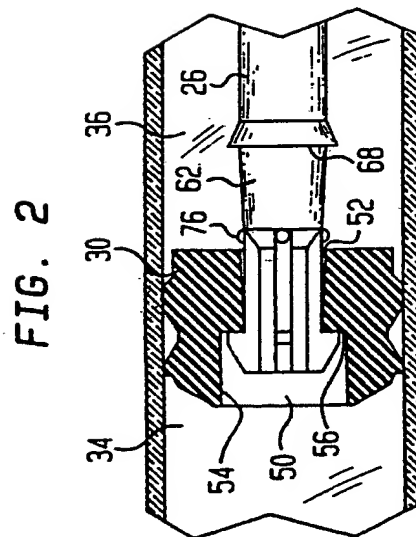
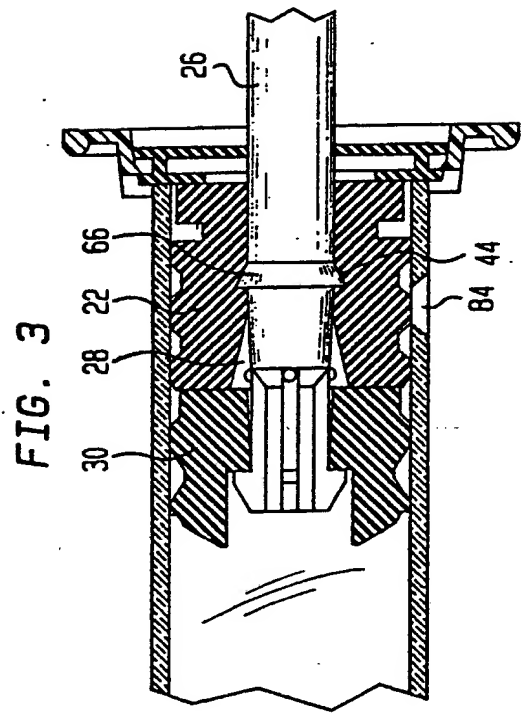
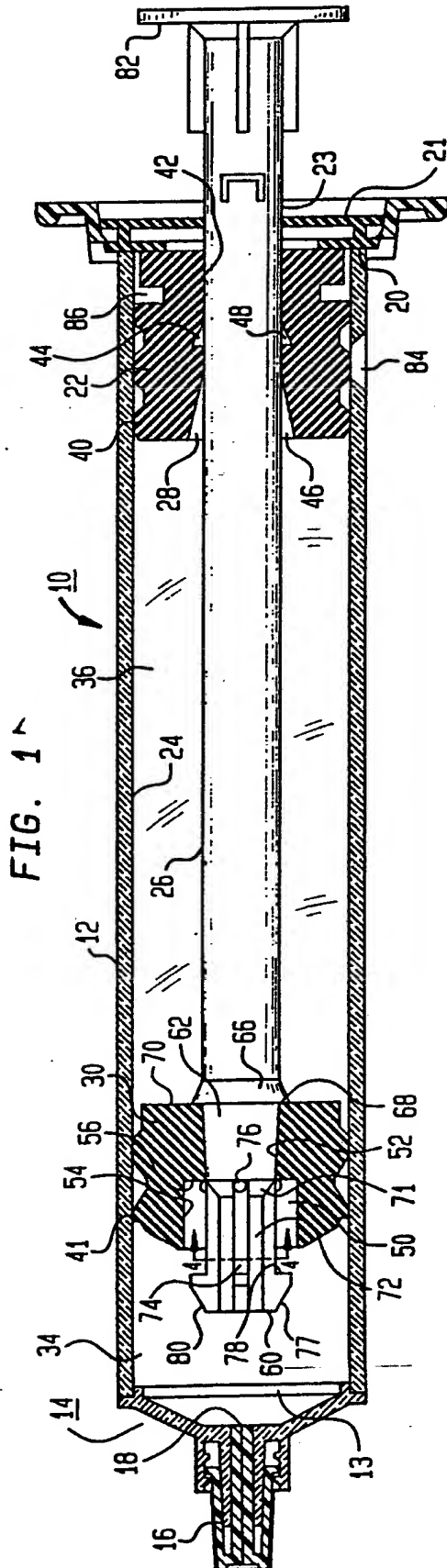


FIG. 5

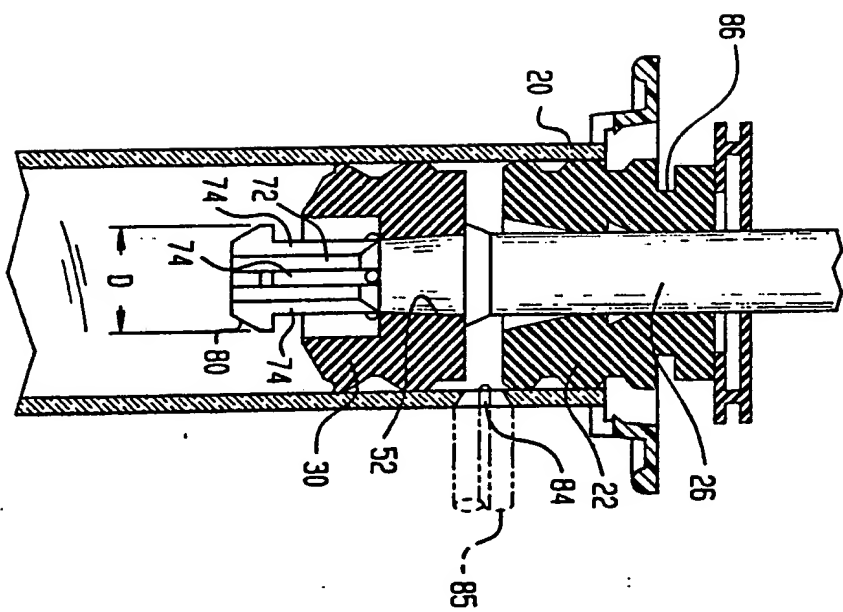
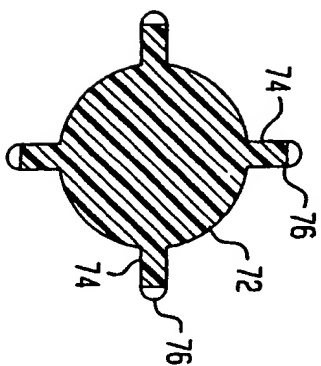
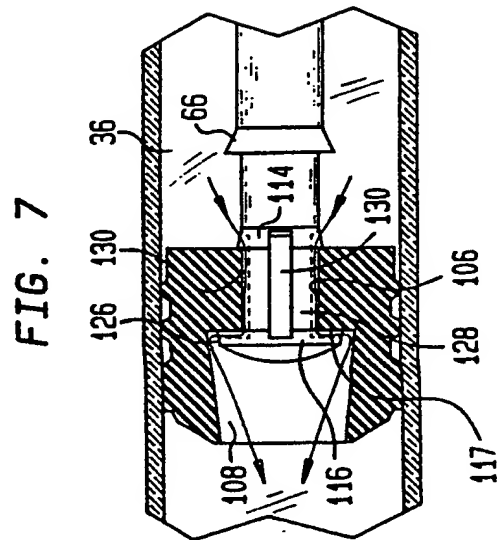
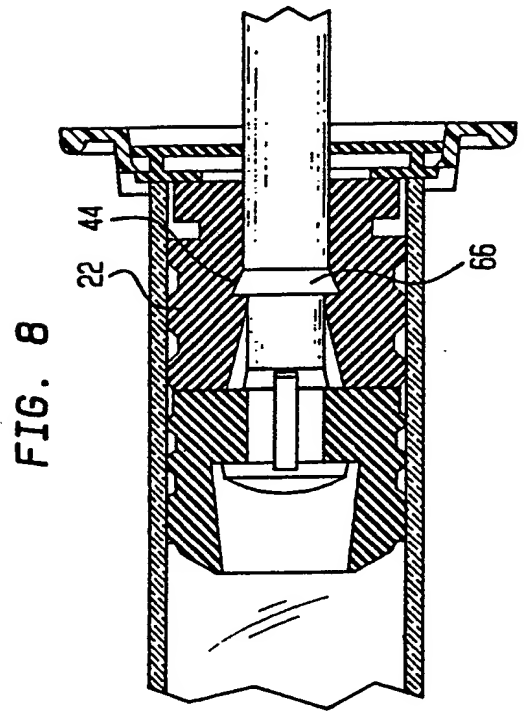
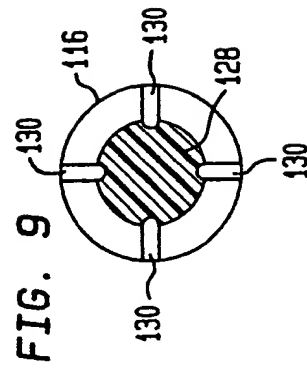
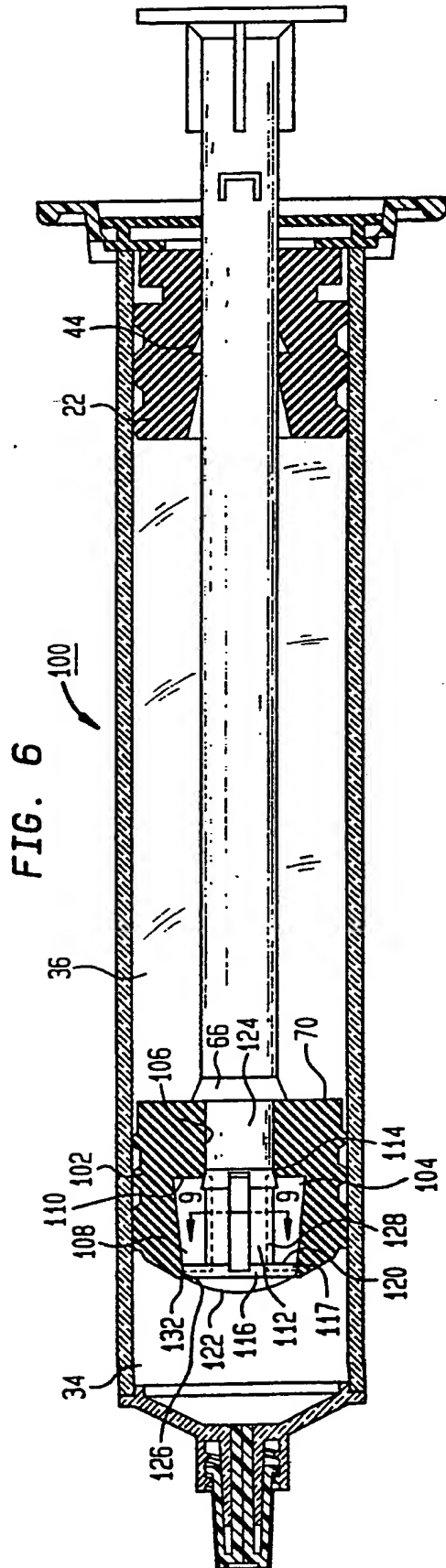


FIG. 4





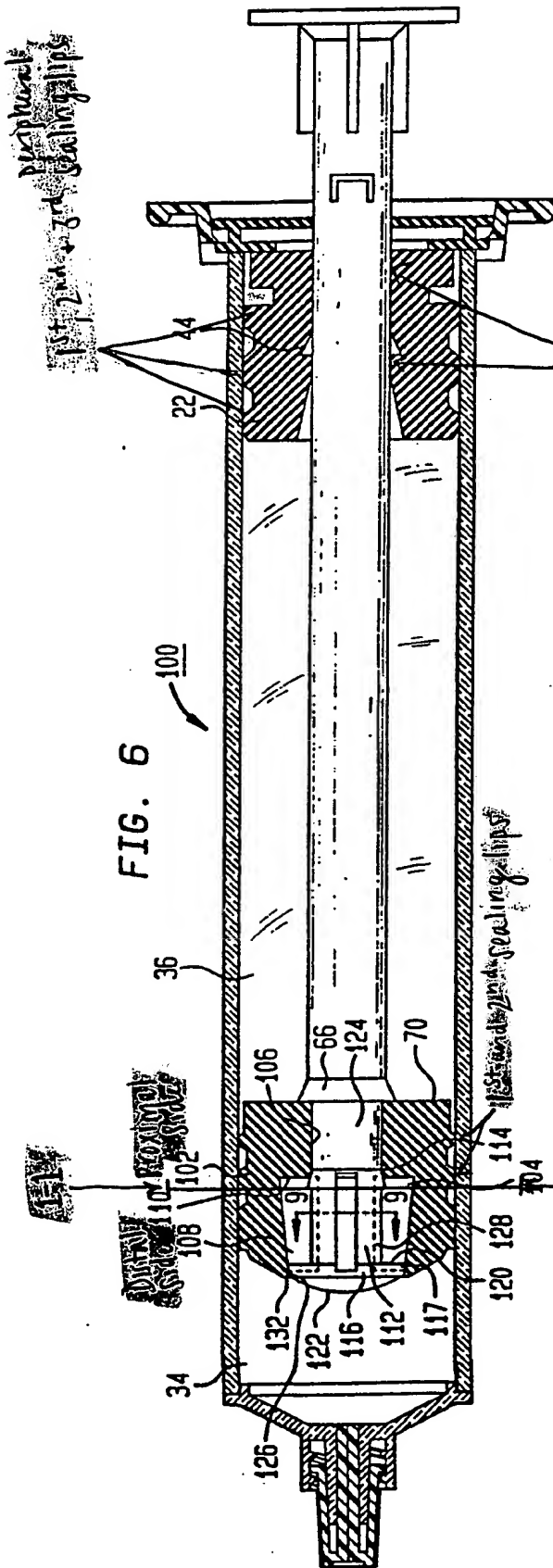


FIG. 6

*1st and 2nd sealing lips
in the center bore*

FIG. 8

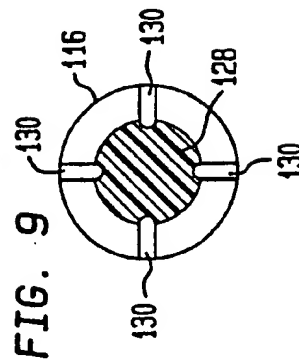
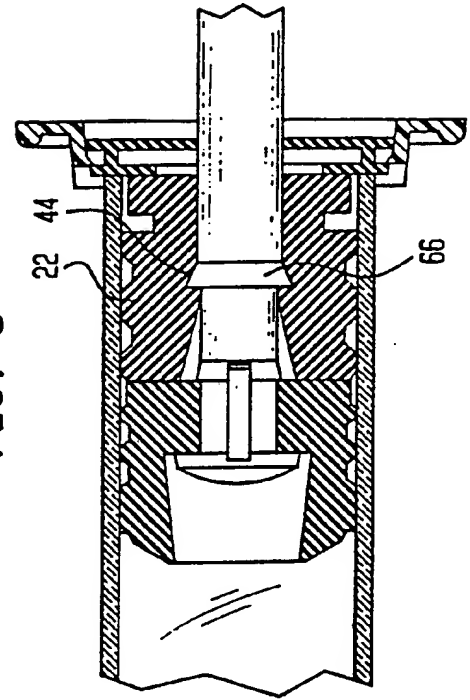
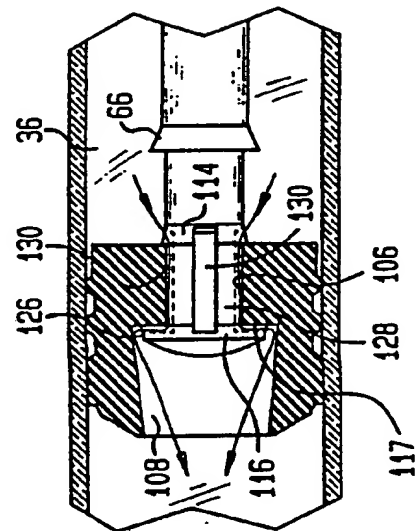





FIG. 9

FIG. 7



INTERNATIONAL SEARCH REPORT

International Application No PCT/US 88/01801

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶ According to International Patent Classification (IPC) or to both National Classification and IPC IPC ⁴ : A 61 M 5/315																							
II. FIELDS SEARCHED <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black;">Minimum Documentation Searched ⁷</div> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; border-bottom: 1px solid black;">Classification System</td> <td style="border-bottom: 1px solid black;">Classification Symbols</td> </tr> <tr> <td style="padding: 5px;">IPC⁴</td> <td style="padding: 5px;">A 61 M</td> </tr> </table> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black;">Documentation Searched other than Minimum Documentation to the extent that such Documents are Included in the Fields Searched ⁸</div>			Classification System	Classification Symbols	IPC ⁴	A 61 M																	
Classification System	Classification Symbols																						
IPC ⁴	A 61 M																						
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹ <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 10%; border-bottom: 1px solid black;">Category ¹⁰</th> <th style="width: 70%; border-bottom: 1px solid black;">Citation of Document, ¹¹ with Indication, where appropriate, of the relevant passages ¹²</th> <th style="width: 20%; border-bottom: 1px solid black;">Relevant to Claim No. ¹³</th> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">X</td> <td style="padding: 5px;">DE, A, 1791293 (PHARMA-GUMMI WIMMER WEST) 18 December 1975, see page 8, line 11 - page 16, line 4; figures 1-5 --</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1-11</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">DE, A, 2329390 (MURDOCH) 3 January 1974, see page 11, lines 16-24; page 15, lines 1-27; figures 7,8 --</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1-11</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">FR, A, 2091684 (HAMPEL) 14 January 1972, see page 5, line 35 - page 6, line 1; figure 1 --</td> <td style="text-align: center; vertical-align: top; padding: 5px;">3,4</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">US, A, 3957051 (TOPHAM) 18 May 1976, see abstract; figures 3,4 --</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1,12</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">EP, A, 0037920 (INTERMEDICAT) 21 October 1981, see figure 3 --</td> <td style="text-align: center; vertical-align: top; padding: 5px;">12,13</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">US, A, 3076456 (HUNT) 5 February 1963 cited in the application -----</td> <td></td> </tr> </table>			Category ¹⁰	Citation of Document, ¹¹ with Indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³	X	DE, A, 1791293 (PHARMA-GUMMI WIMMER WEST) 18 December 1975, see page 8, line 11 - page 16, line 4; figures 1-5 --	1-11	A	DE, A, 2329390 (MURDOCH) 3 January 1974, see page 11, lines 16-24; page 15, lines 1-27; figures 7,8 --	1-11	A	FR, A, 2091684 (HAMPEL) 14 January 1972, see page 5, line 35 - page 6, line 1; figure 1 --	3,4	A	US, A, 3957051 (TOPHAM) 18 May 1976, see abstract; figures 3,4 --	1,12	A	EP, A, 0037920 (INTERMEDICAT) 21 October 1981, see figure 3 --	12,13	A	US, A, 3076456 (HUNT) 5 February 1963 cited in the application -----	
Category ¹⁰	Citation of Document, ¹¹ with Indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³																					
X	DE, A, 1791293 (PHARMA-GUMMI WIMMER WEST) 18 December 1975, see page 8, line 11 - page 16, line 4; figures 1-5 --	1-11																					
A	DE, A, 2329390 (MURDOCH) 3 January 1974, see page 11, lines 16-24; page 15, lines 1-27; figures 7,8 --	1-11																					
A	FR, A, 2091684 (HAMPEL) 14 January 1972, see page 5, line 35 - page 6, line 1; figure 1 --	3,4																					
A	US, A, 3957051 (TOPHAM) 18 May 1976, see abstract; figures 3,4 --	1,12																					
A	EP, A, 0037920 (INTERMEDICAT) 21 October 1981, see figure 3 --	12,13																					
A	US, A, 3076456 (HUNT) 5 February 1963 cited in the application -----																						
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>¹⁴ Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"Δ" document member of the same patent family</p> </div> </div>																							
IV. CERTIFICATION <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; border-bottom: 1px solid black;">Date of the Actual Completion of the International Search</td> <td style="width: 50%; border-bottom: 1px solid black;">Date of Mailing of this International Search Report</td> </tr> <tr> <td style="padding: 5px;">20th September 1988</td> <td style="text-align: center; padding: 5px;">14 OCT 1988</td> </tr> <tr> <td style="border-bottom: 1px solid black;">International Searching Authority</td> <td style="border-bottom: 1px solid black;">Signature of Authorized Officer</td> </tr> <tr> <td style="text-align: center; padding: 5px;">EUROPEAN PATENT OFFICE</td> <td style="text-align: center; padding: 5px;">  P.C.G. VAN DER PUTTEN </td> </tr> </table>			Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	20th September 1988	14 OCT 1988	International Searching Authority	Signature of Authorized Officer	EUROPEAN PATENT OFFICE	 P.C.G. VAN DER PUTTEN													
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report																						
20th September 1988	14 OCT 1988																						
International Searching Authority	Signature of Authorized Officer																						
EUROPEAN PATENT OFFICE	 P.C.G. VAN DER PUTTEN																						

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

US 8801801
SA 23022

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 06/10/88. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE-A- 1791293	18-12-75	None	
DE-A- 2329390	03-01-74	NL-A- 7308086 FR-A, B 2245381 AU-A- 5666273	11-12-73 25-04-75 12-12-74
FR-A- 2091684	14-01-72	NL-A- 7102018 DE-A- 2024117 CH-A- 540698 DE-A, B 2031841 DE-A- 2040789	18-11-71 16-09-71 15-10-73 08-06-72 24-02-72
US-A- 3957051	18-05-76	None	
EP-A- 0037920	21-10-81	None	
US-A- 3076456		None	